IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

ROSA THOMAS	)	**CASE NO.: 04:07-CV-01195**
	)	
Plaintiff,	)	
	)	**JUDGE: LIMBERT**
v.	)	
	)	
PFIZER, INC.	)	
	)	**DEFENDANT PFIZER INC.'S ANSWER TO PLAINTIFF'S ORIGINAL COMPLAINT**
Defendant.	)	
	)	
	)	
	)	**(JURY DEMAND ENDORSED HEREON)**
	)	

Defendant Pfizer Inc. (incorrectly captioned as "Pfizer, Inc.") ("Pfizer") and for its Answer to Plaintiff's Original Complaint ("Complaint") and Jury Demand state as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra®. Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

II.
ORIGINAL ANSWER

Response to Allegations Regarding the Nature of the Case

1. Defendant Pfizer admits during certain periods of time it co-promoted and marketed and promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Except as admitted herein, Defendant Pfizer denies the allegations in Paragraph 1 of Plaintiff's Complaint.

Response to Allegations Regarding Parties and Jurisdiction

2. Defendant Pfizer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 of Plaintiff's Complaint and therefore denies the allegations for want of knowledge.

3. Defendant Pfizer admits it is a Delaware corporation with its principal place of business in New York licensed and registered to do business in the State of Ohio and that it can be served through its statutory agency, CT Corporation System located at 36 East Seventh Street, Suite 240, in Cincinnati, Ohio.

4. Defendant Pfizer denies that it is liable to Plaintiff for any type of damages, in any amount, and further denies the remaining allegations in Paragraph 4 of Plaintiff's Complaint.

5. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant denies the allegations contained in Paragraph 5 of the Complaint.

6. Paragraph 6 of Plaintiff's Complaint states Plaintiff's own assertions and legal conclusions to which no response is required. Defendant denies the remaining allegations contained in Paragraph 6 of Plaintiff's Complaint.

Response to Allegations Regarding Factual Background

7. Defendant Pfizer admits that during certain periods of time it co-promoted and marketed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Except as admitted herein, Defendant Pfizer denies the allegations contained in Paragraph 7 of Plaintiff's Complaint.

8. Defendant Pfizer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of Plaintiff's Complaint that Plaintiff ingested Bextra® or suffered a stroke in June 2004, and therefore denies the allegations for want of knowledge. Defendant Pfizer further denies the remaining allegations in Paragraph 8 of Plaintiff's Complaint. Specifically, Defendant further explicitly denies the allegations in Paragraph 8 of Plaintiff's Complaint relative to Bextra® causing Plaintiff any injuries, specifically, but not limited to cardiovascular, cerebrovascular and myocardial infarction.

9. Defendant Pfizer is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of Plaintiff's Complaint regarding Plaintiff's knowledge and therefore denies the allegations for want of knowledge. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer denies the remaining allegations in Paragraph 9 of Plaintiff's Complaint.

10. Defendant Pfizer admits that during certain periods of time it co-promoted and marketed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Except as admitted herein, Defendant Pfizer denies the allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendant Pfizer admits, as stated in the package insert approved by the FDA, that Bextra® is a nonsterodial anti-inflammatory drug ("NSAID") that exhibits anti-inflammatory, analgesic, and antipryretic properties in animal models and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis, primarily through inhibition of cyclooxygenase-2 ("COX-2"). Defendant Pfizer admits that Bextra® was approved by the FDA on November 16, 2001. Defendant Pfizer admits, as indicated in the package insert approved by the FDA, that that Bextra® was indicated for the use in relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant Pfizer is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11 of Plaintiff's Complaint and therefore denies the allegations for want of knowledge.

12. Defendant Pfizer admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005, at the request of the FDA. Defendant Pfizer denies the remaining allegations in Paragraph 12 of Plaintiff's Complaint.

13. Defendant Pfizer denies the allegations of Paragraph 13 of Plaintiff's Complaint.

14. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer denies the remaining allegations in Paragraph 14 of Plaintiff's Complaint.

15. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing

information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer otherwise denies the allegations in Paragraph 15 of Plaintiff's Complaint.

16. Defendant Pfizer denies the allegations contained in Paragraph 16 of Plaintiff's Complaint.

Responses to Causes of Action

Response to First Cause of Action: Strict Products Liability

17. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 16 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Defendant Pfizer admits that during certain periods of time it co-promoted and marketed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant Pfizer denies the remaining allegations in Paragraph 18 of Plaintiff's Complaint.

19. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant Pfizer denies the allegations in Paragraph 19 of the Complaint.

20. Defendant Pfizer denies that Bextra® is defective and further denies the remaining allegations in Paragraph 20 of Plaintiff's Complaint.

21. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer admits that during certain periods of time it co-promoted and marketed

Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant Pfizer denies that Bextra® is defective and further denies the remaining allegations in Paragraph 21 of Plaintiff's Complaint.

22. Defendant Pfizer denies that Bextra® is defective and further denies the remaining allegations contained in Paragraph 22 of Plaintiff's Complaint, including subparts a, b, and c.

23. Defendant Pfizer denies the allegations contained in Paragraph 23 of Plaintiff's Complaint.

24. Defendant Pfizer denies the allegations contained in Paragraph 24 of Plaintiff's Complaint.

25. Defendant Pfizer denies the allegations contained in Paragraph 25 of Plaintiff's Complaint.

26. Defendant Pfizer denies the allegations contained in Paragraph 26 of Plaintiff's Complaint.

27. Paragraph 27 of Plaintiff's Complaint states Plaintiff's own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations contained in Paragraph 27 of Plaintiff's Complaint for want of knowledge.

28. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer denies the allegations contained in Paragraph 28 of Plaintiff's Complaint.

29. Defendant Pfizer states the Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer denies the allegations in Paragraph 29 of Plaintiff's Complaint.

30. Defendant Pfizer denies the allegations contained in Paragraph 30 of Plaintiff's Complaint.

Response to Second Cause of Action: Negligence

31. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 30 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 31 of Plaintiff's Complaint.

32. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant Pfizer admits that it has duties as are imposed by law, but denies that it breached any such duty. Defendant Pfizer denies the remaining allegations contained in Paragraph 32 of Plaintiff's Complaint.

33. Defendant Pfizer denies the allegations contained in Paragraph 33 of Plaintiff's Complaint, including subparts a and b.

34. Defendant Pfizer denies the allegations contained in Paragraph 34 of Plaintiff's Complaint, including subparts a, b, and c.

35. Defendant Pfizer denies the allegations in Paragraph 35 of Plaintiff's Complaint.

36. Defendant Pfizer denies the allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Defendant Pfizer denies the allegations contained in Paragraph 37 of Plaintiff's Complaint.

Response to Third Cause of Action: Breach of Express Warranty

38. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 37 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer denies the allegations contained in Paragraph 39 of Plaintiff's Complaint.

40. This paragraph contains legal contentions to which no response is required. To the extent that a response is required, Defendant Pfizer denies the allegations contained in Paragraph 40 of Plaintiff's Complaint for want of knowledge.

41. Defendant Pfizer denies the allegations contained in Paragraph 41 of Plaintiff's Complaint.

42. Defendant Pfizer denies that Bextra® caused any injuries or damages to Plaintiff, and denies the remaining allegations contained in Paragraph 42 of Plaintiff's Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty of Merchantability

43. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 42 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 43 of Plaintiff's Complaint.

44. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer denies the allegations contained in Paragraph 44 of Plaintiff's Complaint for want of knowledge.

45. This paragraph contains legal contentions to which no response is required. To the extent that a response is required, Defendant Pfizer denies the allegations contained in Paragraph 45 of Plaintiff's Complaint for want of knowledge.

46. Defendant Pfizer denies the allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. Defendant Pfizer denies that Bextra® caused any injuries or damages to Plaintiff, and denies the remaining allegations contained in Paragraph 47 of Plaintiff's Complaint.

Response to Fifth Cause of Action: Strict Liability, Misrepresentation, and Suppression

48. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 47 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 48 of Plaintiff's Complaint.

49. Defendant Pfizer denies the allegations contained in Paragraph 49 of Plaintiff's Complaint.

50. Paragraph 50 of Plaintiff's Complaint states Plaintiff's own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations contained in Paragraph 50 of Plaintiff's Complaint for want of knowledge.

51. Defendant Pfizer denies the allegations contained in Paragraph 51 of Plaintiff's Complaint, including subparts a, b, and c.

52. Defendant Pfizer denies the allegations contained in Paragraph 52 of Plaintiff's Complaint.

53. Defendant Pfizer denies that Bextra® caused any injuries or damages to Plaintiff, and denies the remaining allegations contained in Paragraph 53 of Plaintiff's Complaint.

Response to Sixth Cause of Action: Negligent Misrepresentation

54. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 53 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 54 of Plaintiff's Complaint.

55. Defendant Pfizer states that Bextra® was safe and effective when used in accordance with the FDA-approved prescribing information. Defendant Pfizer further states that the potential effects of Bextra® were adequately described in the FDA-approved prescribing information that was at all times adequate and comported with applicable standards of care and law. Defendant Pfizer denies the allegations contained in Paragraph 55 of Plaintiff's Complaint.

56. Defendant Pfizer denies the allegations contained in Paragraph 56 of Plaintiff's Complaint, including subparts a and b.

57. Defendant Pfizer denies the allegations contained in Paragraph 57 relative to Pfizer committing misrepresentations and denies for want of knowledge the remaining allegations.

58. Defendant Pfizer denies the allegations contained in Paragraph 58 of Plaintiff's Complaint.

Response to Seventh Cause of Action: Fraud

59. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 58 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 59 of Plaintiff's Complaint.

60. Defendant Pfizer denies the allegations contained in Paragraph 60 of Plaintiff's Complaint.

61. Defendant Pfizer denies the allegations contained in Paragraph 61 of Plaintiff's Complaint.

62. Defendant Pfizer denies the allegations contained in Paragraph 62 of Plaintiff's Complaint.

63. Defendant Pfizer denies the allegations contained in Paragraph 63 of Plaintiff's Complaint.

Response to Eighth Cause of Action: Violation of the Ohio Consumer Sales Practices Act

64. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 63 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 64 of Plaintiff's Complaint.

65. This paragraph contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant Pfizer denies the allegations contained in Paragraph 65 of Plaintiff's Complaint.

66. Defendant Pfizer denies the allegations contained in Paragraph 66 of Plaintiff's Complaint.

67. Defendant Pfizer denies the allegations contained in Paragraph 67 of Plaintiff's Complaint.

68. Defendant Pfizer denies the allegations contained in Paragraph 68 of Plaintiff's Complaint.

Response to Ninth Cause of Action: Negligence Per Se

69. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 68 above as though fully rewritten therein. Defendant denies for want of knowledge the allegations contained in Paragraph 69 of Plaintiff's Complaint.

70. This paragraph states legal contentions to which no response is required. To the extent that a response is deemed required, Defendant Pfizer denies the allegations contained in Paragraph 70 of Plaintiff's Complaint.

71. Defendant Pfizer denies that Bextra® caused any injuries or damages to Plaintiff, or Plaintiff's death, and denies the remaining allegations contained in Paragraph 71 of Plaintiff's Complaint.

72. Defendant Pfizer denies the allegations contained in Paragraph 72 of Plaintiff's Complaint.

III.
AFFIRMATIVE DEFENSES

Defendant Pfizer reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant Pfizer would further show affirmatively that:

1. The Complaint fails to state a claim upon which relief can be granted.

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Pfizer's labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Pfizer, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

3. At all relevant times, Pfizer provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

4. At all relevant times, Pfizer's warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

5. Plaintiff's action is time-barred as it was filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Pfizer.

6. Plaintiff's action is barred by the statute of response.

7. Plaintiff's claims against Pfizer are barred to the extent Plaintiff were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiff should be diminished accordingly.

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Pfizer. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Pfizer and for whose acts or omissions Pfizer is not liable in any way.

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Pfizer cannot be liable.

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

11. Pfizer affirmatively denies that it violated any duty owed to Plaintiff.

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on

the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's treating and prescribing physicians.

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Pfizer and any liability of Pfizer is therefore barred.

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Pfizer.

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

20. Plaintiff is barred from recovering against Pfizer because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

25. Plaintiff's claims are barred in whole or in part because Pfizer provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

30. The imposition of punitive damages in this case would violate Pfizer's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Ohio, and would additionally violate Pfizer's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by Section 2315.21 of the Ohio Revised Code and the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of the Ohio Revised Code.

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

33. Plaintiff's punitive damage claims are preempted by federal law.

34. In the event that reliance was placed upon Pfizer's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Pfizer.

35. Plaintiff failed to provide Pfizer with timely notice of any alleged nonconformance to any express representation.

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Pfizer's rights under the United States Constitution.

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and,

therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Ohio. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant Pfizer; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1

(1991), TXO Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North America, Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S. 408 (2003).

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Pfizer and over whom Pfizer had no control and for whom Pfizer may not be held accountable.

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

44. Plaintiff's claims are barred because her injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses,

subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Pfizer's conduct.

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Pfizer's conduct.

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contend should have been provided.

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources, and the provisions of the Ohio Revised Code.

51. Pfizer's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Pfizer seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

54. Plaintiff's fraud based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure and/or Ohio law.

55. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable to Plaintiff and to nonparties as provided by the Ohio Revised Code.

56. One or more of Plaintiff's claims for damages are subject to statutory limits on certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiff beyond the limitations set forth in the Ohio Revised Code.

57. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiff's claims, including the limits and restrictions on damages set forth herein.

58. Pfizer reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

IV.
PRAYER

WHEREFORE, having fully answered the Complaint, Defendant Pfizer prays that Plaintiff take nothing by her suit; that Defendant Pfizer have judgment for its costs and attorneys' fees incurred herein; and for such other and further relief to which Defendant Pfizer may be justly entitled.

Respectfully submitted,

/s/ Matthew P. Moriarty
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JURY DEMAND

Defendant Pfizer hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

/S/ MATTHEW P. MORIARTY
ONE OF THE ATTORNEYS FOR
DEFENDANT PFIZER INC.

CERTIFICATE OF SERVICE

I hereby certify that on April 30, 2007, a copy of the forgoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. A copy was also sent by regular U.S. Mail to the following:

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